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Charles E. Van Horn
Finnegan, Henderson, Farabow
Garrett & Dunner LLP
901 New York Avenue, NW
Washington DC 20001

In Re: Patent Term Extension
Application for
U.S. Patent No. 7,097,834
Filed: July 27, 2010

REQUIREMENT FOR INFORMATION

The above-identified application for patent term extension ("PTE Application") does not contain certain information as required by 37 C.F.R. § 1.740.

The following requirement has not been complied with sufficiently:

- (1) 37 C.F.R. § 1.740(a)(9) requires a statement that the patent claims the approved product, or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim and **demonstrates** the manner in which at least one such patent claim reads on:
 - (i) The approved product, if the listed claims include any claim to the approved product;
 - (ii) The method of using the approved product, if the listed claims include any claim to the method of using the approved product; and
 - (iii) The method of manufacturing the approved product, if the listed claims include any claim to the method of manufacturing the approved product;

Here, Applicant indicated that certain of the patent claims claim the method of using the approved product and included the text of the patent claims and refers to the U.S. package insert. It is unclear how a product merely described as "a fully humanized monoclonal antibody which binds to human RANKL" in the PTE Application at 1 and on the package insert as "a RANK ligand (RANKL) inhibitor" meets the claim limitation of "an antagonist antibody or binding fragment thereof which binds to the osteoprotegerin binding protein of SEQ ID NO: 39."

A complete response to this notice will provide a narrative which **demonstrates** the manner in which the patent claim(s) reads on the method of using the approved product.

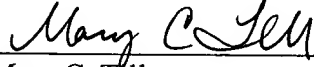
Applicant has **TWO MONTHS** from the date of this letter in order to file a complete reply clarifying the points raised. Extensions of time under 37 CFR 1.136 are available.

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
 P.O. Box 1450
 Alexandria, VA 22313-1450

By FAX: (571) 273-0100
 Attn: Office of Patent Legal Administration

Telephone inquiries related to this notice should be directed to the undersigned at (571) 272-7755.



Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
 Food and Drug Administration
 10903 New Hampshire Ave., Bldg 51, Rm. 6222
 Silver Spring, MD 20993-0002

RE: PROLIA® (denosumab)
Docket No.:

Attn: Beverly Friedman